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510(k) Summary of Safety and Effectiveness for the

ADVIA® Chemistry DRUG Calibrator II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K090900

B. Date of Preparation: December 22, 2008

C. Proprietary and Established Names:

ADVIA® Chemistry DRUG Calibrator II

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Kira Gordon, Sr. Regulatory Affairs Specialist

Office: (914) 524-2996 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Chemistry DRUG Calibrator II

1. Regulation section: 21 CFR § 862.3200 Clinical Toxicology Calibrator.

2. Classification: Class II

3. Product Code: DKB, calibrators, drug mixture

4. Panel: Toxicology

F. Predicate Device:

ADVIA Chemistry TDM DRUG Calibrator II is substantially equivalent to the (formerly) Dade Behring Dimension Drug Calibrator II (DRUG CAL II – DC49D) cleared under K033809.

G. Device Description:

ADVIA Chemistry TDM DRUG Calibrator II is a multi-analyte, liquid, bovine serum based product containing multiple analytes. The kit consists of 2 vials of each of 5 calibrator levels which are ready for use (no preparation is required). The volume per

vial is 5.0 mL. Tobramycin, Carbamazepine, Valproic Acic, Vancomycin and Gentamicin analytes are value assigned for ADVIA Chemsitry systems.

H. Intended Use:

The ADVIA Chemistry TDM DRUG Calibrator II is for *in vitro* diagnostic use in the calibration of Carbamazepine_2 (CARB_2), Gentamicin_2 (GENT_2), Tobramycin_2 (TOBR_2), Valproic Acid_2 (VPA_2), and Vancomycin_2 (VANC_2) methods on the ADVIA Chemistry Systems

I. Substantial Equivalence Information:

The ADVIA Chemistry TDM Drug Calibrator II and Dimension Drug Calibrator II were compared in the following table.

Item	**New Device** - The ADVIA Chemistry TDM Drug II Calibrator	**Predicate Device** - (formerly) Dade Behring Dimension Drug Calibrator II (DC49D)
Intended Use	For *in vitro* diagnostic use in the calibration of Carbamazapine_2 (CARB_2), Gentamicin_2 (GENT_2), Tobramycin_2 (TOB_2), Valproic Acid_2 (VPA_2), and Vancomycin_2 (VANC_2) methods on the ADVIA Chemistry systems.	DRUG CAL II is an in vitro diagnostic product for the calibration of the following methods packaged in the Flex reagent cartridges: acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC).
Formulation / analytes present	carbamazepine, gentamicin, tobramycin, valproic acid, vancomycin	acetaminophen, carbamazepine, digitoxin, gentamicin, lidocaine, N-acetylprocainamide, procainamide, tobramycin, valproic acid, and vancomycin
Measured Analytes (value assigned)	Carbamazepine (CARB_2), Gentamicin (GENT_2). Tobramycin (TOBR_2), Valproic Acid_2 (VPA_2), Vancomycin (VANC_2)	acetaminophen (ACTM), carbamazepine (CRBM), digitoxin (DGTX), gentamicin (GENT), lidocaine (LIDO), N-acetylprocainamide (NAPA), procainamide (PROC), tobramycin (TOBR), valproic acid (VALP), and vancomycin (VANC).
Form	Liquid	Liquid
Traceability	USP	USP
Matrix	Bovine	Bovine
Number of Levels	five	five
Packaging	Ten vials: two vials at five levels (5.0 mL each)	Ten vials: two vials at five levels (5.0 mL each)

Stability	12 months – shelf-life 30 days open vial	12 months – shelf-life 30 days open vial

J. Conclusion:

The multianalyte, five level, bovine serum base ADVIA Chemistry TDM DRUG Calibrator II is substantially equivalent to the Dimension DRUG Calibrator II. They are identical in composition and both used in calibration of TDM on Chemistry systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics, Inc.
c/o Dr. Kira Gordon
511 Benedict Ave
Tarrytown, NY 10591

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Re: k090900
Trade Name: ADVIA Chemistry DRUG Calibrator II
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Codes: DKB
Dated: March 31, 2009
Received: April 1, 2009

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): **k090900**

Device Name: ADVIA Chemistry DRUG Calibrator II

Indication For Use:

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Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090900